

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

JONNIE HOMYK, et al.,

Plaintiffs,

v.

CHEMOCENTRYX, INC., et al.,

Defendants.

Case No. 21-cv-03343-JST

**ORDER RESOLVING MOTIONS TO
EXCLUDE**

Re: ECF No. 188, 190, 191, 193–99, 206

REDACTED VERSION

Before the Court are the parties’ motions to exclude evidence under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). This order addresses Defendants ChemoCentryx, Inc. (“ChemoCentryx”) and Dr. Thomas J. Schall’s (together, “Defendants”) motions to exclude testimony of Dr. Alan Bonder, Dr. Simon Helfgott, Dr. David Madigan, and Dr. Matthew Cain, and Lead Plaintiff Indiana Public Retirement System’s motions to exclude testimony of Dr. Anisha Dua, Dr. Naga Chalasani, Dr. Lindsay Lally, Dr. Steven Weisman, Dr. Robert Gibbons, Dr. Anupam Jena, and Mr. Carl Seiden. ECF Nos. 188, 190, 191, 193–99, 206.

The Court will deny the motion as to Cain and grant the motions as to Jena and Lally. The Court will grant in part and deny in part the remainder of the motions.

I. BACKGROUND¹

Lead Plaintiff Indiana Public Retirement System brings this action individually and on behalf of all persons who purchased or otherwise acquired ChemoCentryx common stock between November 26, 2019, and May 6, 2021, inclusive (“Class Period”). Plaintiff alleges that ChemoCentryx and Dr. Schall, its President and Chief Executive Officer, violated Sections 10(b)

¹ The facts are taken from the allegations in the complaint unless otherwise stated.

1 and 20(a) of the Securities Exchange Act of 1934 by making false and misleading statements and
 2 omissions about the safety, efficacy, and application for Food and Drug Administration (“FDA”)
 3 approval of a proprietary vasculitis drug called avacopan, thereby artificially inflating the price of
 4 ChemoCentryx stock during the Class Period. Plaintiff also alleges that Dr. Schall is liable for
 5 insider trading under Section 20A of the Securities Exchange Act.

6 ChemoCentryx is a pharmaceutical company specializing in drugs designed to treat rare
 7 diseases. ECF. No. 47 ¶ 5. The company developed avacopan, which Defendants presented as a
 8 breakthrough therapy for the treatment of ANCA-associated vasculitis (“AAV”), a rare
 9 autoimmune disease. *Id.* Physicians had been treating AAV with a combination of steroids and
 10 immunosuppressants. *Id.* ¶ 48. Defendants described avacopan as a drug that would transform the
 11 standard of care for AAV, in part by replacing steroid treatment, the long-term use of which
 12 presented safety risks for patients. *Id.* ¶ 1.

13 At the start of the Class Period, Defendants announced the results of a study called
 14 ADVOCATE, the Phase III trial of avacopan for the treatment of AAV. *Id.* ¶ 10. ADVOCATE
 15 was designed to provide evidence to support ChemoCentryx’s application for FDA approval of
 16 avacopan. *Id.* ¶ 2. Throughout the Class Period, Defendants stated that trial safety results showed
 17 that avacopan was safer than standard-of-care steroid therapy; that, in the trial, avacopan had
 18 demonstrated non-inferiority versus prednisone with respect to the primary endpoint of
 19 Birmingham Vasculitis Activity Score (“BVAS”) remission at week 26 and superiority at week
 20 52; that the study demonstrated that chronic steroids were not needed to achieve remission; and
 21 that communications with the FDA regarding the avacopan New Drug Application (“NDA”) had
 22 been straightforward. *Id.*

23 However, in private communications with Defendants in 2016 and 2020, the FDA had
 24 expressed concerns about the trial’s design and results. The FDA repeatedly told Defendants that
 25 ADVOCATE was “likely not adequate” to demonstrate, or even assess, whether using avacopan
 26 as a “replacement for glucocorticoids [] will provide an improved benefit-risk profile.” *Id.* ¶ 86.
 27 Specifically, the FDA told Defendants that statistical non-inferiority would be inadequate to
 28 demonstrate that avacopan could replace the steroid-based standard of care, casting doubt on the

1 sufficiency of ADVOCATE’s key week 26 results. *Id.* ¶¶ 96–100. The FDA also warned
 2 Defendants that ADVOCATE’s relapse data was unreliable because those analyses failed to
 3 preserve study randomization and were not adjusted for multiplicity. *Id.* ¶¶ 101–03, 110–22. The
 4 FDA further indicated “that avacopan was efficacious only in the population who did not receive
 5 standard-of-care maintenance,” raising questions about the meaning of the study’s results.
 6 *Id.* ¶¶ 107–08.

7 Plaintiff alleges that Defendants knowingly withheld adverse facts from investors during
 8 the Class Period. For example, Plaintiff alleges that Defendants knew that steroid use was
 9 significant and widespread among avacopan patients enrolled in the trial. *Id.* ¶¶ 138–46. The
 10 majority of avacopan patients were prescribed the steroid prednisone during the trial to control
 11 their vasculitis, and ChemoCentryx considered such patients to have responded to avacopan in its
 12 analysis of trial data, despite their significant steroid use. *Id.* Plaintiff alleges that Defendants
 13 knew that these adverse facts undermined their public statements about the comparative safety and
 14 efficacy of avacopan and standard-of-care steroid therapy. *Id.* Plaintiff also alleges that
 15 Defendants knew of and failed to disclose serious adverse liver events, including an event meeting
 16 Hy’s Law criteria² and one occurring after rechallenge, that occurred during the trial. ECF No.
 17 47 ¶ 128. Further, Plaintiff alleges that ChemoCentryx did not disclose its failure to follow trial
 18 protocol in calculating remission results. When these results were later calculated in accordance
 19 with trial protocol, avacopan failed to achieve superiority to standard-of-care steroid therapy at
 20 week 52 by a statistically significant margin. *Id.* ¶¶ 130–37.

21 Plaintiff alleges that Defendants’ misleading statements about the success of the avacopan
 22 trial and the prospective NDA submission artificially inflated ChemoCentryx’s stock price during
 23 the Class Period, enriching both Dr. Schall and ChemoCentryx. During the 17-month Class
 24
 25

26 ² “A Hy’s Law case involves significant elevations in both a patient’s serum levels of
 27 aminotransferase (enzyme leaked by injured cells) and increases in bilirubin, indicating the liver
 28 injury is significant enough to impair liver function. . . . [T]he occurrence of even one case
 meeting Hy’s Law criteria in a clinical trial is enough to raise red flags, as these cases often
 predict severe post[-]marketing liver toxicity.” ECF No. 202-29 at 22-23 (footnote omitted).

Period, Dr. Schall sold more than 893,300 shares of ChemoCentryx stock—representing nearly 20% of his ChemoCentryx holdings—and earned proceeds of over \$40.3 million. *Id.* ¶¶ 152–54.

The market learned the extent of the FDA’s concerns about the trial in early May 2021. On May 4, the FDA published the Briefing Book and other materials (together, “Advisory Committee Materials”) in advance of its Advisory Committee meeting. The concerns reflected in these documents mirrored many of the concerns the FDA had privately expressed to ChemoCentryx in 2016 and 2020. *Id.* ¶ 17. These materials further revealed, among other things, the extent of steroid use among avacopan patients in the trial. *Id.* In response to the release of the Advisory Committee Materials, ChemoCentryx’s common stock dropped more than 45% in a single day. *Id.* ¶ 18. Analysts and investors expressed surprise at the scope of the FDA’s criticism of the trial and the fact that ChemoCentryx had not disclosed the FDA’s concerns. *Id.*

On May 6, 2021, the Advisory Committee held a public meeting to discuss avacopan. The Advisory Committee meeting revealed that ADVOCATE’s supposed “superiority” results were the product of violations of the prespecified trial rules. *Id.* ¶ 19. This meeting, Plaintiff alleges, also allowed investors to appreciate the significance of the previously concealed facts discussed in the FDA Briefing Book, including the clinical import of the ADVOCATE results. *Id.* Advisory Committee members were evenly split on the question of whether the drug should be approved, and those who voted in favor of approval argued its label should be limited—that is, that it should only be approved for use by a limited set of patients. The next day, ChemoCentryx common stock fell by approximately 62%. *Id.*

Overall, ChemoCentryx’s share price fell 79% over four days, from \$48.82 on May 3, 2021, to \$10.46 on May 7, 2021. *Id.* ¶ 20. This caused massive losses to investors, including Plaintiff. The FDA ultimately approved avacopan for use only in conjunction with steroids and only by adult patients with severe active AAV. *Id.* ¶¶ 21–23. The FDA also required ChemoCentryx to include warnings for liver toxicity on the avacopan label and ordered ChemoCentryx to conduct three post-marketing studies to evaluate liver toxicity. *Id.*

On October 8, 2021, approximately five months after the end of the Class Period, the FDA approved avacopan for the market under the trade name of TAVNEOS. *Id.* ¶ 191. Plaintiff

alleges that the FDA approved the drug “with a far more limited label than ChemoCentryx had hoped: with an indication as only an adjunct therapy to steroid-based standard of care in patients with severe vasculitis” and with a disclaimer that the drug “does not eliminate glucocorticoid use.” *Id.*

As this Court has previously noted, Plaintiff challenges four overlapping categories of Defendants’ statements as misleading due to omitted facts: (1) statements about the ADVOCATE trial’s safety results; (2) statements about the trial’s efficacy results, namely statements suggesting that avacopan achieved the trial’s BVAS primary endpoint and demonstrated superior BVAS remission as compared to prednisone; (3) statements about the trial’s design and avacopan’s ability to replace steroid therapy; and (4) statements about the avacopan NDA and the company’s communications with the FDA. ECF No. 61 at 13. Defendants argue that their statements were not misleading and that any alleged omissions were corrected by their public disclosures during the Class Period, including in an article they published in the *New England Journal of Medicine* (“*NEJM*”) in February 2021.

II. JURISDICTION

The Court has jurisdiction under 28 U.S.C. § 1331.

III. LEGAL STANDARD

The proponent of expert testimony “has the burden of proving admissibility.” *Lust ex rel. Lust v. Merrell Dow Pharms., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). Under Rule 702 of the Federal Rules of Evidence:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Following *Daubert*, 509 U.S. 579, trial courts serve a “gatekeeping” role “to ensure the reliability and relevancy of expert testimony.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). “Expert opinion testimony is relevant if the knowledge underlying it has a valid connection to the pertinent inquiry. And it is reliable if the knowledge underlying it has a reliable basis in the knowledge and experience of the relevant discipline.” *Alaska Rent-A-Car, Inc. v. Avis Budget Grp., Inc.*, 738 F.3d 960, 969 (9th Cir. 2013) (quoting *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010)). The question “is not the correctness of the expert’s conclusions but the soundness of his methodology.” *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995). Thus, courts should “screen the jury from unreliable nonsense opinions, but not exclude opinions merely because they are impeachable.” *Alaska Rent-A-Car*, 738 F.3d at 969. “Shaky but admissible evidence is to be attacked by cross examination, contrary evidence, and attention to the burden of proof, not exclusion.” *Primiano*, 598 F.3d at 564.

IV. DISCUSSION

A. Post-Class Period Events Regarding TAVNEOS

As a threshold matter, the parties dispute the relevance and admissibility of expert testimony by Lindsay Lally, Anisha Dua, Naga Chalasani, Steven Weisman, Anupam Jena, and Simon Helfgott regarding post-Class Period events. *See* ECF Nos. 192-3, 192-4, 192-7, 192-8, 192-9, 202-6. These events include the FDA’s approval of avacopan for the market as TAVNEOS, the nature of TAVNEOS’s label, the safety and efficacy of TAVNEOS, and the scope of TAVNEOS’s usage by physicians. *Id.*

Plaintiff argues that because TAVNEOS was approved—and thus used—five months after the end of the Class Period, expert testimony on TAVNEOS’s approval, label, efficacy, or usage does not relate to the issues in this case, i.e., whether Defendants made misrepresentations about the ADVOCATE trial, avacopan, or its interactions with the FDA *during the Class Period*. *See, e.g.*, ECF No. 192-3 at 11–12.

Defendants largely offer two responses. First, Defendants argue that the FDA’s post-Class Period approval of avacopan is relevant as to the falsity of their alleged misstatements and omissions because it shows that Defendants’ interpretation of the safety and efficacy data from the

ADVOCATE trial was reasonable. *See, e.g.*, ECF No. 227-9 at 27–28 (citing *In Re Phillip Morris Int’l Inc. Sec. Litig.*, 89 F.4th 408, 422 (2d Cir. 2023)). Second, Defendants argue that it was Plaintiff who first put TAVNEOS’s safety and efficacy, as well as the scope of its approved label, at issue. In support, Defendants cite allegations in the amended consolidated class action complaint, Plaintiff’s class certification briefing, and various opinions contained in Plaintiff’s expert reports. *See* ECF No. 227-7 at 17–19. So, they argue, “[h]aving chosen to implicate post-Class Period events in its theory of the case, and to seek recovery based on the post-Class Period label for TAVNEOS, Plaintiff must now accept the relevance of post-Class Period evidence offered in response to its allegations.” *Id.* at 19.

In its various reply briefs, Plaintiff represents that it will *not* introduce evidence of post-Class Period events at trial as long as Defendants are prohibited from doing the same. *See, e.g.*, ECF No. 237-3 at 12. Plaintiff further argues that it is not judicially estopped from arguing that Defendants’ experts should be excluded from testifying about the usefulness of TAVNEOS based on fleeting references in its complaint, evidence it sought in discovery, or a “handful of opinions” in its expert reports that were included “in response to Defendants’ anticipated arguments about the significance of the FDA’s label.” *See* ECF No. 237-3 at 9–11. Finally, Plaintiff argues that the inclusion of testimony about TAVNEOS would lead to a mini-trial about an issue entirely tangential to the misrepresentations involved in this case about the ADVOCATE trial and avacopan. *See id.* at 8–9.

Having examined the cases cited by the parties, the expert reports in dispute, and the underlying claims at issue, the Court does not now exclude testimony about the meaning or significance of the FDA’s approval of TAVNEOS regarding what the FDA concluded about avacopan’s overall safety and/or risk-benefit profile based on the ADVOCATE trial. *See* ECF No. 192-14 ¶ 27 (Chalasani opining that the FDA’s approval of avacopan “serves as an important indicator that the FDA found that the benefits of avacopan outweigh its potential risks for the intended population, including any hepatotoxicity risk”); ECF No. 192-10) ¶¶ 31 (Weisman opining that the “FDA’s approval necessarily means FDA analyzed avacopan’s risk benefit profile and found it acceptable.”), 128 (Weisman opining that the FDA’s approval of avacopan confirms

that avacopan’s overall safety profile was acceptable). This category of testimony may be relevant to Plaintiff’s allegation that Defendants misrepresented the safety profile for avacopan based on ADVOCATE’s top-line safety results during the Class Period. *See, e.g.*, ECF No. 47 ¶¶ 70, 219, 246. At trial, the Court will be better able to assess the relevance and risk of confusing the issues, misleading the jury, or wasting time. *See* Fed. R. Evid. 401, 403. If it determines that such evidence should be admitted, the Court will likely give the jury limiting instructions concerning the purposes for which the evidence can be considered.

As to the remaining expert testimony regarding the nature of TAVNEOS’s label, the safety and efficacy of TAVNEOS, and the scope of TAVNEOS’s usage by physicians in the post-Class Period, the Court does not find this testimony to be relevant to whether Defendants made misrepresentations based on the ADVOCATE trial results. Testimony on post-Class Period developments also runs the risk of creating jury confusion and making the trial difficult to manage. The Court will thus exclude expert testimony on TAVNEOS’s efficacy, its label, or the scope of its usage by clinicians as irrelevant. *See Alberici v. Recro Pharma, Inc.*, No. CV 18-2279, 2021 WL 798299, at *7 (E.D. Pa. Mar. 1, 2021) (finding that evidence about a drug two years after the end of the Class Period “does not indicate that the statements were not false or misleading at the time they were made”) (emphasis in original); *Hsu v. Puma Biotechnology, Inc.*, 2018 WL 11669124, at *2 (C.D. Cal. Oct. 24, 2018) (excluding evidence of “post-Class Period events, results, or outcomes”).³

B. Defendants’ Motion to Exclude the Testimony of Dr. David Madigan

David Madigan, Ph.D., is a statistician with research experience in the field of drug safety and pharmacovigilance, or the science of detecting, assessing, and preventing adverse events from medical therapies. Defendants move to exclude Madigan from offering opinions that [REDACTED]; that ChemoCentryx should have disclosed more about a “safety signal” from the ADVOCATE trial in the *NEJM* article published in

³ Defendants may be allowed to introduce testimony on post-Class Period developments as reasonably necessary to rebut any evidence or testimony that Plaintiff introduces or “opens the door” to at trial on the same topics.

February 2021; and that are comprised of narrative characterizations of the facts. *See* ECF No. 202-4 at 9–11.

To the extent that Defendants argue that Madigan’s opinion is based on “inadequate and misleadingly partial facts,” ECF No. 202-4 at 16, these objections go to the weight of Madigan’s opinion and not its admissibility, and Defendants are better suited cross-examining Madigan on the purported flawed factual basis of his opinion at trial. *See Wroth v. City of Rohnert Park*, No. 17-cv-05339, 2019 WL 1766163-JST, at *4 (N.D. Cal. April 22, 2019) (“To the extent those unreviewed materials undermine [the expert’s] conclusions, that challenge goes ‘to the weight of the testimony and its credibility, not its admissibility.’”) (quoting *Alaska Rent-A-Car, Inc. v. Avis Budget Group, Inc.*, 738 F.3d 960, 970 (9th Cir. 2013)).

1 [REDACTED]
2 [REDACTED]
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14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]

21 Next, Defendants similarly seek to exclude as irrelevant and unreliable Madigan’s opinion
22 that ChemoCentryx should have disclosed more about a liver toxicity safety signal from the
23 ADVOCATE trial in the *NEJM* article published in February 2021. *See* ECF No. 202-4 at 28–29.
24 Plaintiff counters that Madigan’s opinion on this subject is relevant and necessary to rebut
25 Defendants’ “truth-on-the-market” defense in which they contend that they had disclosed the
26 alleged concealed information about the ADVOCATE design and results and observed adverse
27 events in the published *NEJM* article. *See* ECF No. 220-5 at 26–29. Specifically, Madigan would
28 contextualize to a jury the function that ChemoCentryx’s Data Monitoring Committee (“DMC”)

1 performed in the clinical trial and explain the significance of the letter that the DMC sent to
2 ChemoCentryx objecting to ChemoCentryx’s “superficial” disclosure of avacopan’s
3 hepatotoxicity risk in the *NEJM* article.

4 The Court agrees with Plaintiff in part. Madigan may testify about the function of the
5 DMC because it would help the jury understand the disagreements that arose regarding observed
6 adverse events in the ADVOCATE trial. *See In re Bard IVC Filters Prods. Liab. Litig.*, 2017 WL
7 6523833, at *5-6; *In re Yasmin & YAZ (Drospirenone) Mktg., Sales Prac. & Prods. Liab. Litig.*,
8 No. 3:09-MD-02100-DRH, 2011 WL 6302287, at *17 (S.D. Ill. Dec. 16, 2011) (explaining that an
9 FDA regulatory expert’s “testimony would not be useless to the jury” and, instead, “will certainly
10 be helpful to the jury’s understanding of this complicated industry”). And he may interpret the
11 DMC letter regarding the *NEJM* article as well as rebut Defendants’ characterization of the
12 disclosures made in the *NEJM* article if Defendants put the article at issue at trial. But Madigan
13 may not testify that the *NEJM* article was “affirmatively scientifically misleading,” ECF No.
14 192- 20 ¶ 75, or that ChemoCentryx *should have*—as opposed to did or did not—disclosed a liver
15 safety signal on avacopan in the *NEJM* article because those opinions are irrelevant to the issues in
16 this case regarding misrepresentations to *investors* and are outside the bounds of Madigan’s
17 expertise.

18 Finally, Defendants object that Madigan’s opinions are “plagued by excessive narration
19 and commentary on the facts” and that many of his opinions “are simply a recitation and
20 characterization of Plaintiff’s version of the facts and a timeline of events.” ECF No. 202-4 at 29.
21 Defendants thus argue that this “kind of baseless commentary on the facts is not proper expert
22 opinion” and should be excluded. *See id.* at 30.

23 An expert may apply special expertise to help the jury understand the structure of complex
24 and unfamiliar regulatory frameworks, like the clinical trials and their governing protocols here.
25 *See Holley v. Gilead Scis., Inc.*, No. 18-CV-06972-JST, 2023 WL 2469632, at *6 (N.D. Cal. Feb.
26 27, 2023); *see also In re Bard.*, 2017 WL 6523833, at *6 (noting that “FDA procedures are
27 beyond the ken of average jurors”); *In re Yasmin*, 2011 WL 6302287, at *17.

28 However, as this Court has explained before, “much of the material in the regulatory

history is likely ‘properly presented through percipient witnesses and documentary evidence.’” *Holley*, 2023 WL 2469632, at *6 (*In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 551 (S.D.N.Y. 2004)). And an expert may not “merely read, selectively quote from, or regurgitate the evidence.” *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (quotation marks omitted). But an expert’s testimony may include “explaining the regulatory context in which [documents and exhibits in evidence] were created, defining any complex or specialized terminology, [and] drawing inferences that would not be apparent without the benefit of experience or specialized knowledge.” *Id.* “Whether narrative or summary testimony will be admitted at trial is ‘context specific’ and will be decided at a later date, but ‘if evidence is admitted in narrative or summary form, [the opposing party] will have an opportunity during cross-examination or presentation of its own evidence to address any concerns [it] might have.’” *Holley*, 2023 WL 2469632, at *6 (quoting *In re Yasmin*, 2011 WL 6302287, at *13). Indeed, “an objection to the ‘narrative’ nature of testimony is an objection [that] . . . is properly asserted at trial [I]t is not a proper objection to an *expert report*, that, itself, will not be placed into evidence, nor to a *Daubert* challenge.” *In re Actos (Pioglitazone) Prods. Liab. Litig.*, No. 12-cv-00064, 2014 WL 120973, at *14 (W.D. La. Jan. 10, 2014) (emphasis in original).

C. Plaintiff’s Motion to Exclude Testimony of Dr. Lindsay Lally

Defendants retained Lindsay Lally, M.D., to respond to opinions offered by Plaintiff’s experts, Dr. Helfgott and Mr. Ragab, as well as to offer her own opinions about physicians’ usage of TAVNEOS to treat patients with AAV. Plaintiff seeks to exclude the following opinions of Lally: (1) that TAVNEOS is a “useful” drug for treating AAV and (2) that the TAVNEOS label is expansive, not restrictive. The Court will grant Plaintiff’s motion to exclude those opinions.

As discussed above, Lally may not testify about TAVNEOS’s label and usefulness because that testimony is irrelevant to whether Defendants made misrepresentations during the Class Period and runs the risk of confusing the jury. Having excluded the challenged opinions on grounds of relevance, the Court need not reach Plaintiff’s other arguments for why Lally’s opinions should be excluded.

D. Plaintiff's Motion to Exclude the Testimony of Dr. Anisha Dua

Defendants plan to introduce Anisha Dua, M.D., to “offer affirmative opinions and to respond to the opinions of Drs. Helfgott, Bonder, Walton, and Madigan regarding the ADVOCATE trial’s design, TAVNEOS’s risk-benefit profile, and TAVNEOS’s FDA-approved label.” ECF No. 227-4 at 9. Dua is a rheumatologist who specializes in treating vasculitis. ECF No. 192-12 ¶ 1. As part of her clinical practice, she treats dozens of AAV patients per month and regularly consults with other rheumatologists about AAV and TAVNEOS. *See id.* ¶¶ 2–5.

Plaintiff moves to exclude Dua from offering the following opinions from her report: (1) TAVNEOS has a “clear net benefit” for patients suffering from AAV; (2) the TAVNEOS label was “not restrictive” and “not unexpected” by clinicians, and did not limit how clinicians use TAVNEOS to treat AAV; (3) clinicians believed the FDA’s approval of TAVNEOS reflected the “evolving treatment landscape” for AAV; (4) the “regulatory and medical community” believed TAVNEOS⁴ had an “acceptable” safety profile; and (5) clinicians are accustomed to dealing with TAVNEOS’s safety concerns and view the drug as a tool to reduce steroid use. *See* ECF No. 192-7 at 2–3 (internal quotation marks omitted).

First, Plaintiff argues that Dua’s opinion regarding the net benefit of TAVNEOS is irrelevant. For the reasons discussed above on post-Class Period events, the Court will exclude Dua from offering opinions regarding the net benefit of TAVNEOS.

Second, Plaintiff argues that Dua’s opinions on the scope of TAVNEOS’s label and the prescribing practices of clinicians regarding TAVNEOS are inadmissible because Dua is not qualified to “opine on how regulatory labeling issues would impact other physicians’ prescribing behavior, and her opinions lack a reliable methodological basis.” ECF No. 192-7 at 16.

Defendants respond that Dua is qualified to “speak to the interpretation and impact of the TAVNEOS label within her own practice and those of her physician colleagues” because she regularly treats AAV patients, prescribes TAVNEOS, and “creates educational content and

⁴ Because the parties use “TAVNEOS” interchangeably with “avacopan” in the briefing, the Court adopts Plaintiff’s framing of the challenged opinions but distinguishes in its analysis opinions regarding avacopan during the Class Period and TAVNEOS after the Class Period.

1 treatment guidelines for other physicians on these same topics.” ECF No. 227-4 at 19. The Court
2 agrees with Plaintiff. While Dua may be qualified to speak about her personal experience with
3 prescribing TAVNEOS, she cannot reliably testify as to the beliefs or practices of other
4 physicians. *See In re: Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab.*
5 *Litig.*, No. MDL 1203, 2000 WL 876900, at *12 (E.D. Pa. June 20, 2000) (“The court can easily
6 preclude, from a Daubert viewpoint, the rendering of opinions by either of these witnesses . . . as
7 to what doctors in general think, because the witnesses are not qualified for that.”). Furthermore,
8 while Plaintiff does not appear to specifically challenge these opinions on relevance, the Court
9 finds that the same relevance issues regarding TAVNEOS generally apply here. Thus, Dua’s
10 opinions on the scope of TAVNEOS’s label and the prescribing practices of clinicians regarding
11 TAVNEOS are also excluded on relevance grounds.

12 Third, Plaintiff argues that Dua’s opinions about what the “regulatory and medical
13 community” believed regarding the AAV treatment landscape, avacopan’s safety profile, and the
14 implications for steroid usage when considering avacopan are inadmissible because Dua is “not
15 qualified to testify about the views or beliefs of the medical community as a whole.” ECF No.
16 192-7 at 19. Defendants contend that Dua is merely “offering views of TAVNEOS and its uses
17 based on her own firsthand specialized experience and those of physicians with whom she
18 regularly works and consults and who have shared their feedback with her.” ECF No. 227-4 at 21.
19 Again, while Dua may testify about her personal understanding of avacopan, she cannot reliably
20 testify as to how other physicians view or understand avacopan—let alone what the “medical
21 community” believes. *See Holley*, 2023 WL 2469632, at *11 (excluding expert testimony on what
22 an “average clinician” would be able to order or what such a clinician “would likely think”); *In re:*
23 *Diet Drugs*, 2000 WL 876900, at *12 (same); *Medtronic, Inc. v. Axonics Modulation Techs., Inc.*,
24 No. SA CV 19-02115-DOC-JDE, 2024 WL 4406929, at *21 (C.D. Cal. Aug. 29, 2024)
25 (explaining that the court anticipated precluding the expert “from relying on anecdotal evidence
26 from other doctors” but allowing the expert “to opine based on his own experience and that of his
27 own patients”).
28

E. Defendants' Motion to Exclude the Testimony of Dr. Simon Helfgott

Simon Helfgott, M.D., is the Director of Education and Fellowship Training in the Division of Rheumatology, Immunity, and Inflammation at Brigham and Women's Hospital, where he oversees an active rheumatology clinic and supervises both patient care and the training of newer rheumatologists. ECF No. 202-29 ¶¶ 1, 7–9.

Defendants move to exclude Helfgott from offering opinions on the following: (1) how clinicians view avacopan; (2) [REDACTED] 3) ChemoCentryx's misrepresentation of facts in the *NJEM* article; and (4) the mental states of ChemoCentryx and its employees.⁵ Defendants further argue that Helfgott's opinions feature extensive improper narrative and argument, which should be excluded.

As a threshold matter, although Defendants have not raised a relevance challenge to the portions of Helfgott's testimony regarding the post-Class Period usage of TAVNEOS, the Court will apply the same parameters to all expert testimony in this case and preclude Helfgott from testifying about that subject matter, including about TAVNEOS's FDA label.

First, Plaintiff acknowledges that Helfgott will not offer opinions at trial about the views of the entire "medical community" or what "all doctors think of avacopan," but that he will "testify at trial about the important clinical considerations that would be relevant to physicians in deciding whether to prescribe avacopan." ECF No. 220-4 at 15. For the reasons discussed above as to Dua, Helfgott may not improperly speculate by testifying about how the medical community or other clinicians view or would view avacopan's safety in the face of certain data. *See, e.g.*, ECF No. 220-36 ¶¶ 40, 58, 75, 103, 116. However, just as with Dua, he may testify about his own understanding of avacopan and data from the ADVOCATE trial, including his considerations on whether to use the drug for AAV treatment from a clinician's perspective. *See, e.g., id.* ¶¶ 42–43 ("From a clinical perspective, the significant increase in the incidence of both serious and combined adverse hepatobiliary adverse events in patients taking avacopan raises a concerning

⁵ Plaintiff agreed in their opposition that Helfgott would "not be offering opinions at trial about the motives and intentions of ChemoCentryx or its employees." ECF No. 220-4 at 15. Accordingly, Helfgott's opinions in paragraphs 53, 96, 107, 110, and 112 are excluded to the extent that they express opinions about the "mental states" or "motives" of ChemoCentryx or its employees.

liver safety signal with the drug.”).

Third, Defendants argue that Helfgott’s opinions that ChemoCentryx misrepresented facts important to a clinician’s understanding of avacopan’s safety risks, including in the *NEJM* article, should be excluded because they are irrelevant and improperly reach an ultimate issue. ECF No. 248-5 at 16. The Court agrees in part. As Defendants appear to concede, experts may provide testimony as to the “accuracy” of challenged statements, including the “objective truth or falsity of statements based on their specialized or scientific knowledge.” *In re Cryolife, Inc. Sec. Litig.*, 2005 WL 8155579, at *7 (N.D. Ga. June 17, 2005). Accordingly, as to the statements Defendants made to investors during a series of calls and meetings regarding the safety and efficacy of avacopan and the design of the ADVOCATE trial, Helfgott may testify—from his perspective as a clinician—about the scientific accuracy of those statements. And his usage of the term “misrepresent” does not have such a specialized meaning in the context of securities fraud claims that it constitutes an impermissible legal conclusion. *See United States v. Diaz*, 876 F.3d 1194, 1198–99 (9th Cir. 2017) (“We hold that if the terms used by an expert witness do not have a

1 specialized meaning in law and do not represent an attempt to instruct the jury on the law, or how
2 to apply the law to the facts of the case, the testimony is not an impermissible legal conclusion.”).

3 As to the portion of Helfgott’s opinion regarding the *NEJM* article, the Court’s reasoning
4 above applies here—Helfgott may interpret the accuracy of the substance within the *NEJM* article
5 since “Defendants maintain that this publication discloses much of the information Plaintiff
6 alleges was concealed from the market,” ECF No. 248-5 at 18. But Helfgott may not testify that
7 “[c]linicians expect a sponsor’s publication of clinical trial results to fully disclose both the
8 benefits and especially the risks of a novel therapy, so that the reader can decide their significance
9 and make an informed decision about the drug’s merits,” ECF No. 202-29 ¶ 125, because
10 clinicians’ expectations for what should be disclosed is not at issue in this case.

11 Finally, consistent with the discussion regarding Madigan, the Court denies Defendants’
12 motion to exclude testimony by Helfgott on grounds that it contains improper narrative or
13 argument. “Objections to specific questions or testimony may be raised at trial if appropriate.”
14 *Holley*, 2023 WL 2469632, at *6.

15 **F. Plaintiff’s Motion to Exclude Testimony of Dr. Naga Chalasani**

16 Naga Chalasani, M.D., is a hepatologist who serves as the Principal Investigator for the
17 U.S. Drug-Induced Liver Injury (“DILI”) Network and has written many articles on DILI,
18 including studies about the prevalence and risks of DILI for specific drugs. He has also served as
19 a member of Advisory Committees for the FDA as a liver safety expert and been involved in data
20 monitoring and hepatic adjudication committees for clinical trials. ECF No. 227-3 at 9.
21 Defendants plan to introduce Chalasani to offer affirmative opinions on the safety data from the
22 ADVOCATE trial and respond to Bonder’s opinions regarding the liver toxicity risk of avacopan
23 as reflected in the ADVOCATE trial. *Id.* at 8–9.

24 Plaintiff seeks to exclude Chalasani from testifying about whether avacopan had an
25 acceptable and manageable hepatotoxicity risk; the meaning of avacopan’s approval by the FDA
26 and other regulatory agencies; the import of the approved TAVNEOS label in relation to
27 avacopan’s hepatotoxicity risk; and instances of DILI in the ADVOCATE trial that were
28 attributable to the antibiotic Bactrim in patients who did not receive avacopan, i.e., in the group of

1 patients receiving prednisone. *See* ECF No. 192-8 at 2–3.

2 Consistent with the discussion above on the relevance of post-Class Period testimony, the
3 Court does not now exclude Chalasani from testifying about avacopan’s approval by the FDA.
4 However, Chalasani may not testify about avacopan’s approval by other foreign health regulatory
5 agencies or about what TAVNEOS’s approved label suggests about avacopan’s hepatotoxicity
6 risk, for lack of relevance and the risk of confusion.

7 As to Chalasani’s opinion about avacopan’s hepatotoxicity risk and risk-benefit
8 assessment, Plaintiff argues that Chalasani’s opinion is unreliable because he cannot perform a
9 risk-benefit analysis of avacopan given that he “failed to independently analyze [avacopan’s]
10 benefits.” *See* ECF No. 237-8 at 14–15. But the Court agrees with Defendants that Chalasani
11 may opine on one side of the risk-benefit equation—the safety risk of avacopan—without
12 conducting an overall risk-benefit assessment of avacopan. *See* ECF No. 227-3 at 13; *see also*,
13 *e.g.*, ECF No. 192-14 ¶¶ 37 (“The clinical trial results also show that all patients who experienced
14 liver injury had full recovery under the appropriate protocol. In the ADVOCATE clinical trial,
15 nine patients in the avacopan group were suspected to have experienced serious adverse events of
16 elevated liver tests.”), 39 (“A review of the trial data reveals only minor imbalances in the
17 incidence of liver biochemistry abnormalities between the avacopan and the control groups,
18 demonstrating acceptable and manageable hepatotoxicity risk of avacopan.”). Chalasani’s
19 assessment on the hepatotoxicity risk of avacopan is sufficiently reliable given his extensive
20 background in matters of liver safety. *See In re: Tylenol (Acetaminophen) Mktg., Sales Pracs., &*
21 *Prods. Liab. Litig.*, No. 2436, 2016 WL 4039286, at *6 (E.D. Pa. July 28, 2016) (allowing an
22 expert to testify regarding whether a risk of a drug was known, “the magnitude of that risk, what
23 actions could or should be taken to reduce the risk, and whether the drug company had undertaken
24 risk reduction measures”).

25 Lastly, Plaintiff moves to preclude Chalasani from testifying that “three patients in the
26 prednisone arm of the ADVOCATE study experienced DILI as a result of taking Bactrim, an
27 antibiotic taken by some patients in the ADVOCATE study.” ECF No. 192-8. Plaintiff argues
28 that exclusion is warranted because this opinion did not appear in Chalasani’s report and was

1 raised for the first time at his deposition, and Chalasani did not identify the materials forming the
 2 basis of this new testimony. *Id.* at 17–19. Defendants counter that Chalasani opined in his report
 3 that Bactrim is a “well-known” cause of DILI and that it was a potential cause of DILI for specific
 4 adverse events in ADVOCATE, and he testified in his deposition consistent with his report in
 5 response to Plaintiff’s counsel questioning him directly about whether any patients in the
 6 prednisone group suffered DILI from Bactrim. *See* ECF No. 227-3 at 25–27. Defendants thus
 7 argue that Chalasani is allowed to elaborate upon his report through oral testimony—particularly
 8 at Plaintiff’s eliciting. *Id.* at 25. The Court agrees with Defendants. Chalasani opines in his
 9 report that Bactrim was a potential cause of DILI for patients in the prednisone arm of
 10 ADVOCATE. ECF No. 192-14 ¶¶ 23, 68–71, 74, 79, 84. His further testimony that there were
 11 three patients in the prednisone arm of ADVOCATE who were suspected of Bactrim DILI is
 12 consistent with his opinions in the report and supported by the report of Dr. Lewis—another
 13 hepatologist retained by ChemoCentryx—that was cited by Chalasani and disclosed to Plaintiff.
 14 *See* ECF No. 202-34 at 106. To the extent that Plaintiff has criticisms about any perceived
 15 inconsistency or inadequate basis for this opinion, it may cross-examine Chalasani at trial or
 16 introduce contrary evidence. *See Primiano*, 598 F.3d at 564.

17 **G. Defendants’ Motion to Exclude Testimony of Dr. Alan Bonder**

18 Plaintiff intends to offer the testimony of Alan Bonder, M.D., to opine on “various
 19 hepatologic issues related to avacopan, the ADVOCATE trial, and the May 6, 2021 FDA
 20 Advisory Committee meeting.” ECF No. 202-31 ¶ 1.

21 Defendants seek to exclude Bonder from offering various opinions about (1) the liver
 22 toxicity signal on avacopan observed in ADVOCATE; (2) ChemoCentryx’s statements being
 23 misleading to the scientific and medical community; (3) the state of mind of Dr. Schall and Dr.
 24 Bekker; and (4) the safety of avacopan based on post-FDA approval data. *See generally* ECF No.
 25 202-5.

26 First, Defendants argue that Bonder’s opinions on liver safety data from ADVOCATE
 27 should be excluded because they merely parrot the opinions of other individuals and are not based
 28 on his own independent analysis of patient files. *See* ECF No. 202-5 at 16–23. Plaintiff responds

1 that Bonder does perform his own review of patient data from ADVOCATE to opine on the
2 adverse liver safety observations and only notes that his opinions are consistent with those of other
3 individuals cited. *See* ECF No. 220-6 at 15–16. The Court agrees with Plaintiff.

4 While Bonder does note the contemporaneous assessments and warnings offered by the
5 DMC and ChemoCentryx’s scientists, he supports his opinion on liver safety data from
6 ADVOCATE with an independent analysis of the underlying patient files. *See, e.g.*, ECF No.
7 202-31 ¶¶ 60–61. Defendants’ objections that Bonder’s testimony contains improper narrative or
8 is cumulative of the testimony offered by other witnesses or the factual record are better made at
9 trial. *See In re Actos*, 2014 WL 120973, at *14. And to the extent that Defendants argue that
10 Bonder’s opinion is unreliable because the review of patient files he performed was not as
11 comprehensive as the review he performs in his regular practice, *see* ECF No. 248-3 at 8–9, this
12 critique goes to the weight of his testimony and not its admissibility. *See Wroth*, 2019 WL
13 1766163-JST, at *4; *In re Twitter, Inc. Sec. Litig.*, 2020 WL 13863616, at *5.

14 The foregoing analysis applies equally to Defendants’ argument that Bonder’s analysis and
15 recitation of the FDA regulatory history should be excluded because they are based on “a
16 misleading and incomplete selection of FDA documentation and correspondence. *See Wroth*,
17 2019 WL 1766163-JST, at *4. However, because Bonder is a medical doctor and not an FDA
18 regulatory expert, he is limited to testifying about the medical significance of the FDA’s
19 observations and discussions—and not about the regulatory context or implications of the FDA’s
20 actions. *See Holley*, 2023 WL 2469632, at *3 (allowing an expert who had extensive experience
21 working at the FDA to testify about the regulatory history in that case *based on his experience at*
22 *the FDA*).

23 Defendants also challenge portions of Bonder’s opinion on liver safety data where he
24 testifies about the statistical significance of events observed in ADVOCATE because he relied on
25 an undisclosed source for that statistical conclusion, and Defendants have been unable to test the
26 reliability of that source. Bonder testified at his deposition that he relied upon “the help of a
27 statistician” provided by “plaintiff’s counsel” to conduct the statistical significance calculation in
28 various portions of his report, but he was unable to identify the statistician by name. *See* ECF No.

202-35 at 241:1-19, 242:20-243:22. Plaintiff now states in its opposition that Bonder relied on Madigan for those statistical analyses. *See* ECF No. 220-6 at 19–20. But attorney argument presented in a legal brief is not evidence. *See Gilmore v. Wells Fargo Bank N.A.*, No. C 14-2389 CW, 2014 WL 3749984, at *3 (N.D. Cal. July 29, 2014). And Bonder’s report makes no reference to Madigan in either its body or in the list of relied upon materials. *See generally* ECF No. 202-31. Accordingly, Bonder is excluded from offering opinions about the challenged statistical analyses that he did not perform independently. *See Toomey v. Nextel Comms., Inc.*, 2004 WL 5512967, at *4 (N.D. Cal. Sept. 23, 2004) (explaining that expert reports must “disclose the data and other information considered by the expert” and that a “party who fails to make the requisite disclosures bears the burden of showing substantial justification for such failure”).

Regarding Defendants’ challenge to Bonder’s opinions that ChemoCentryx’s statements “created a significant risk of misleading members of the scientific and medical communities,” Plaintiff responds that Bonder does not opine as to what the entire medical community believes but only on “what facts are important to a reasonable physician’s assessment of the liver safety of avacopan.” *See* ECF No. 220-6 at 23–27. The Court agrees in part. As a doctor experienced in dealing with liver disease, Bonder may testify as to how *he* would interpret the warnings and data on liver safety that were produced during ADVOCATE from a clinical perspective. *See, e.g.*, ECF No. 202-31 ¶ 83 (“These warnings, provided by competent and independent experts, would have clearly signaled to a reasonable doctor and scientist that there was a significant risk that avacopan was associated with substantial liver toxicity.”). And he may testify as to what safety signals physicians would generally consider when assessing the safety of a drug like avacopan. *See In re Bard*, 2017 WL 11696720, at *4–5 (allowing an expert to testify about what physicians in general expect to see on a label). But he may not opine on how the “scientific and medical communities,” or other physicians would react to those warnings or data, or offer an opinion as to the views of other physicians generally. *See, e.g.*, ECF No. 202-31 ¶¶ 85 (“[D]isclosure of those facts would have significantly weakened the medical community’s view of the drug’s safety profile.”), 86 (“I agree that ChemoCentryx’s statements regarding avacopan’s safety . . . created a significant risk of misleading members of the scientific and medical communities.”); *see also In re: Diet Drugs*,

2000 WL 876900, at *12 (excluding expert testimony on what other physicians would think).

Next, Defendants argue that Bonder should be excluded from improperly opining as to the mental state of Dr. Tom Schall and Dr. Pirow Bekker. The Court agrees with Plaintiff that Bonder may testify about “the meaning and significance of the safety data known to ChemoCentryx,” ECF No. 220-6 at 27, but Bonder may not go further and opine as to what ChemoCentryx (or its employees and consultants) knew. For example, Bonder may testify about the warnings asserted by the “unanimous ADVOCATE DMC, Dr. Maddrey, and other ChemoCentryx advisors,” ECF No. 202-31 ¶ 77, and use his expertise to interpret the significance and meaning of those warnings for the jury. But he may not go on to offer an opinion that ChemoCentryx was in fact “alerted . . . that avacopan was associated with a strong liver toxicity signal,” *id.*, because that goes to ChemoCentryx’s state of mind and invades upon the province of factual determinations that the jury can make. *See Holley*, 2023 WL 2469632, at *9 (allowing an expert to testify about “what knowledge was available to” the defendant but not what the defendant was or was not “aware” of or “understood”).

Finally, for the reasons discussed previously, Bonder may not testify about the safety of avacopan based on an analysis of post-Class Period data on TAVNEOS. Because Defendants’ experts are precluded from offering data regarding the safety and efficacy of TAVNEOS, Bonder’s purported rebuttal testimony on the same is not relevant.

H. Plaintiff’s Motion to Exclude the Testimony of Dr. Steven Weisman

Steven Weisman, Ph.D., is trained as a clinical pharmacologist. *See* ECF No. 192-10 at 5. He has worked and consulted for pharmaceutical development companies and has been involved in the development or regulatory approval process for hundreds of drugs, including those for inflammatory disorders and autoimmune conditions. *See id.* at 5–6.

Plaintiff moves to exclude his testimony regarding the following: (1) opinions about avacopan’s safety and efficacy based on the FDA’s approval of TAVNEOS after the end of the Class Period; (2) the intent and mental states of the FDA, the Japanese Pharmaceuticals and Medical Devices Agency (“PMDA”), and ChemoCentryx; (3) characterizations of ChemoCentryx’s interactions with the FDA as “positive;” (4) the standard of care for treatment of

1 AAV; and (5) his opinion that the FDA’s approval of the design of ADVOCATE created a
2 presumption that the trial was sufficient in objective and design for approval of avacopan.

3 First, for the reasons previously discussed, the Court does not now exclude testimony
4 regarding what the FDA found about avacopan’s safety profile based on its approval of
5 TAVNEOS.

6 Second, regarding Weisman’s opinions about what the FDA or PMDA did, an expert may
7 not testify in a way that would lead to “impermissible speculation as to the state of mind of the
8 FDA.” *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 466 (S.D.N.Y. 2016). But an
9 expert may testify “as to what the FDA did, and what it said, based on the documents he
10 reviewed,” and may “opine on these documents, including what they mean.” *Id.*; *see also Holley*,
11 2023 WL 2469632, at *5. Furthermore, an expert’s testimony may include “explaining the
12 regulatory context in which [documents] were created, defining any complex or specialized
13 terminology, [and] drawing inferences that would not be apparent without the benefit of
14 experience or specialized knowledge.” *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164,
15 192 (S.D.N.Y. 2009).

16 Weisman may thus opine on the FDA’s usual practices, including in the context of the
17 development of drugs for rare diseases, the regulatory options at the FDA’s disposal, and what the
18 FDA did in this case. *See* ECF No. 192-10 ¶¶ 30–46 (“FDA guidance and practice recognizes that
19 flexibility is warranted in the requirements for well-controlled and adequate trials when ‘a better
20 design is not feasible or ethical’”). But he may not testify that “if FDA did not believe at this
21 stage that avacopan should be approved, it would not have planned to hold an advisory committee
22 meeting,” ECF No. 192-10 ¶ 86; that “if the PMDA (or any regulatory authority) found
23 ChemoCentryx’s data verification and cleaning processes problematic, it would have continued to
24 ask for information or refused to approve the drug,” *id.* ¶ 121; that “[h]ad FDA thought that the
25 secondary endpoints would diminish avacopan’s risk-benefit profile, . . . it would not have agreed
26 with the design of the trial and would not have allowed ADVOCATE to go forward,” *id.* ¶ 124; or
27 that “if FDA still had ‘significant’ concerns about the liver safety issues even though it approved
28 the drug, FDA would have included on the approved label for the drug a black box warning,” *id.* ¶

128. “These types of opinions would impermissibly speculate about the FDA’s state of mind” by opining as to *why* the FDA did or did not take certain actions. *See Holley*, 2023 WL 2469632, at *5. Similarly, Weisman may opine on what drug sponsors typically consider during the drug approval process, but he may not opine generally as to what ChemoCentryx’s intent or beliefs were during the regulatory process. *See id.* at *4.

Third, Weisman opines that “ChemoCentryx’s interactions with the FDA before the Advisory Committee Meeting were positive” based on his general experience of having “attended hundreds of meetings with the FDA and foreign regulatory authorities.” ECF No. 227-9 at 14–15. While the Court recognizes Weisman’s experience with the FDA regulatory process, Weisman’s general characterizations of FDA meetings as “positive” is not sufficiently tied to his expertise to be reliable and runs the risk of impermissibly invading the province of the jury. Indeed, “[e]xpert testimony is inadmissible if it addresses lay matters which a jury is capable of understanding and deciding without the expert’s help.” *Aya Healthcare Servs., Inc. v. AMN Healthcare, Inc.*, 613 F. Supp. 3d 1308, 1322 (S.D. Cal. 2020) (quoting *In re Novatel Wireless Secs. Litig.*, No. 08-cv-1689, 2011 WL 5827198, at *4 (S.D. Cal. Nov. 17, 2011)). Accordingly, Weisman may explain the meaning and import—in the context of the drug approval process—of specific portions of the FDA meeting minutes he has reviewed or of ChemoCentryx’s communications with the FDA, but he may not opine generally as to whether certain meetings were overall “positive.”

Fourth, Weisman may not opine as to what the standard of care treatment for AAV was during the Class Period. Defendants concede that Weisman is not a medical doctor and that he “is not opining about what medical doctors viewed as standard of care at the time the ADVOCATE trial was designed.” ECF No. 227-9 at 22. They suggest that he is instead “assessing how the standard of care for treatment ‘can impact the path for drug development by factoring into clinical trial design, NDA submission, and the overall regulatory process.’” *Id.* (quoting ECF No. 192-10 ¶ 6). The Court agrees in part that Weisman has the expertise to opine generally regarding how the standard of care treatment can impact drug development and the overall regulatory process. But Weisman goes beyond that in his report by testifying that “while rituximab may *now* be the standard of care, at the time the ADVOCATE trial was designed, the standard of care was as I just

described – an immunosuppressant (like cyclophosphamide or rituximab) given along with high-dose glucocorticoids.” *See* ECF No. 192-10 ¶ 23. As the standard of care treatment for AAV is disputed in this case, and Weisman does not offer any reliable methodology or expertise for settling that dispute (and he purports not to be offering such an opinion at all), he may not opine that “an immunosuppressant (like cyclophosphamide or rituximab) given along with high-dose glucocorticoids” was the standard of care at the time of ADVOCATE’s design.

Finally, Weisman opines that “the fact that FDA approved the design of ADVOCATE created a presumption that the trial was sufficient in objective and design for approval of avacopan,” citing 21 C.F.R. 312.47(b)(1)(v) in his report. *See* ECF No. 192-10 ¶ 102. At his deposition, Weisman first testified that he had not reviewed 21 C.F.R. 312.47(b)(1)(v) in connection with preparing his report. *See* ECF No. 192-11 at 248:24–249:6. But Weisman later corrected his testimony and stated that he did review the cited regulation in preparing his report. *See id.* at 501:9-17. Weisman also testified that he relied on his general “understanding and experience with end of Phase II meetings and their significance” in rendering his opinions. *Id.* at 248:4-8.

Plaintiff argues that Weisman’s opinion regarding the “presumption” created by the FDA’s approval of the design of ADVOCATE should be excluded because it is an improper legal conclusion and attorney argument. *See* ECF No. 237-4 at 19. While Weisman’s testimony regarding the presumption reflects a presumption created by law, his testimony is also based on his own experiences with the FDA regulatory process. And because he does not appear to offer any instruction on a *legal* presumption, the Court declines to exclude his testimony on this basis. To the extent that Plaintiff believes that Weisman’s opinion has no basis other than in the federal regulation, it can cross-examine Weisman at trial accordingly.

I. Plaintiff’s Motion to Exclude Testimony of Dr. Robert Gibbons

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Plaintiff also argues that Gibbons should be precluded from testifying until he has disclosed the “nature and full extent of the payments related to this matter that he is entitled to receive from Cornerstone Research, an expert support firm retained by Defendants.” *See* ECF No. 237-6 at 17.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The Court thus finds that Plaintiff’s objections go to the weight of Gibbons’s testimony and do not demonstrate that his opinion is so incomplete as to be inadmissible. *See Hemmings v. Tidyman’s Inc.*, 285 F.3d 1174, 1188 (9th Cir. 2002) (explaining that “objections to the inadequacies of a study are more appropriately considered an objection going to the weight of the evidence rather than its

1 admissibility”).

2 Next, Plaintiff argues that Gibbons should be excluded from offering his “multivariate”
3 regression that was first disclosed in his deposition because it is untimely and prejudicial.
4 Defendants respond that Gibbons offered his multivariate analysis as a rebuttal to Madigan’s *reply*
5 report, so he could not have disclosed it in his own report. ECF No. 227-5 at 18–19. Moreover,
6 they contend that there was no prejudice because Plaintiff could have sought to re-open Gibbons’s
7 deposition to question him about the multivariate analysis but did not do so, and there were still
8 several months before trial. *Id.* at 19. The Court disagrees with Defendants’ characterization.
9 The criticism that Gibbons’s multivariate regression ostensibly responds to—the ADVOCATE
10 trial not correcting for multiplicity, ECF No. 227-5 at 18—was disclosed in Madigan’s opening
11 report, *see* ECF No. 202-7 ¶¶ 52–59. Indeed, Gibbons had the chance to respond to this criticism
12 and did so in his report. *See* ECF No. 192-18 ¶ 16. That he thought of another means of
13 responding to the criticism following Madigan’s reply report does not mean he is entitled to offer
14 that opinion.

15 Nor does the Court share Defendant’s assumption that late disclosure can always be cured
16 by allowing an additional deposition. As Plaintiff points out, reopening depositions runs the risk
17 of “blowing up” the schedule that the parties knew about and agreed to regarding the proper time
18 for expert discovery. “Disruption to the schedule of the court and other parties in that manner is
19 not harmless. Courts set such schedules to permit the court and the parties to deal with cases in a
20 thorough and orderly manner, and they must be allowed to enforce them, unless there are good
21 reasons not to.” *Oracle Am., Inc. v. Hewlett Packard Enter. Co.*, No. 16-CV-01393-JST, 2019
22 WL 468809, at *4 (N.D. Cal. Feb. 6, 2019) (quoting *Wong v. Regents of Univ. of Cal.*, 410 F.3d
23 1052, 1062 (9th Cir. 2005)). Accordingly, Gibbons may not offer his multivariate analysis at trial.

24 Regarding the standard of care treatment, Defendants contend that Gibbons is not offering
25 a medical opinion about the standard of care treatment at all such that there is nothing to exclude.
26 *See* ECF No. 227-5 at 20. Accordingly, and consistent with the Court’s discussion as to Weisman,
27 Gibbons may not opine at trial about what the standard of care for AAV during the ADVOCATE
28 trial was.

As to the disclosure of Gibbons's compensation, the Court orders that the parties meet and confer regarding the production of Cornerstone's compensation arrangement with Defendants as reasonably necessary to determine the full extent of Gibbons's own compensation in this case.

J. Plaintiff's Motion to Exclude Testimony of Dr. Anupam Jena

Defendants plan to introduce Anupam Jena, M.D., Ph.D., to respond to Plaintiff's expert Ahmed Ragab's opinions regarding the scope of the label that the FDA approved for TAVNEOS. *See* ECF No. 227-6. Each of Jena's opinions challenged by Plaintiff relate to the post-Class Period usage of TAVNEOS, including Jena's opinion about: (1) the commercial value of TAVNEOS; (2) whether analysts expected a potential label expansion and a high degree of off-label use of TAVNEOS; (3) whether TAVNEOS is likely to receive a label expansion; and (4) health care providers being likely to prescribe TAVNEOS off-label. *See* ECF No. 192-9 at 21. Accordingly, consistent with the reasons discussed above regarding the relevance of testimony about TAVNEOS, the Court grants Plaintiff's motion to exclude the challenged opinions of Jena.

K. Plaintiff's Motion to Exclude Testimony of Carl Seiden

Defendants plan to introduce the testimony of Carl Seiden to evaluate and respond to the opinions offered by Plaintiff's experts regarding what information was known to investors at various points in time regarding ADVOCATE and avacopan. Seiden has worked for decades with and for biopharmaceutical company investors, including fourteen years as a pharmaceutical industry stock market analyst. *See* ECF No. 192-16 ¶¶ 1–6.

Plaintiff moves to exclude six of Seiden's opinions on the grounds that Seiden: (1) improperly speculates about analysts' state of mind; (2) offers irrelevant and unreliable opinions that Defendants' disclosures about ADVOCATE and avacopan were consistent with "industry practice;" and (3) improperly discusses analyst reports from after the Class Period. *See generally* ECF No. 192-5.

First, the Court is unpersuaded by Plaintiff's state of mind challenge regarding Seiden's opinions on what analysts "understood." As Defendants argue, "Seiden does not opine on any particular analyst's 'state of mind,' but rather what information the analysts contemporaneously documented was known and available to investors." ECF No. 227-8 at 16; *see, e.g.*, ECF No. 192-

16 ¶¶ 77–81 (analyzing specific analyst reports from Wells Fargo and Raymond James to support opinion that “analyst reports reflect that equity analysts understood that the advocate study was not designed to prove that avacopan could fully replace use of steroids”). That issue is precisely the one on which Plaintiff’s experts also seek to opine. *See* ECF No. 237-5 at 8 (“Dr. Cain and Mr. Ragab offer opinions concerning the actual content of analyst reports—they do not speculate as to what analysts would have understood or expected. *See* ECF No. 200-24 ¶¶54-55 (citing the text of J.P. Morgan and Piper Jaffray reports to support proposition that ChemoCentryx’s value was linked to the ADVOCATE trial’s results).”). The Court thus declines to exclude Seiden’s opinions on what “analysts”—or the market—understood based on the available contemporaneous documents. *See Optronic Techs., Inc. v. Ningbo Sunny Elec. Co.*, No. 5:16-CV-06370-EJD, 2019 WL 4780183, at *7 (N.D. Cal. Sept. 30, 2019), *aff’d*, 20 F.4th 466 (9th Cir. 2021) (allowing an expert to “offer[] a rebuttal of the testimony of [the opposing party’s] damages expert by testing an input that [the opposing party] put at issue”).

Second, regarding Seiden’s opinion on the biopharmaceutical industry practice of what is typically shared with investors, the Court’s previous analysis in *In re Twitter* is instructive:

The Court concludes that Coates’ testimony regarding customs and practices among large public companies with respect to the preparation of public disclosures is relevant to the question of whether Defendants acted with scienter, because it bears on the question of whether Defendants’ disclosures were an extreme departure from the standards of ordinary care with respect to public disclosures. . . . Accordingly, Coates’ opinions on this topic are not subject to exclusion on the basis that they are irrelevant.

Nor are Coates’ opinions on this topic subject to exclusion on the basis that they are unreliable. Coates’ testimony is based on his knowledge and decades of experience advising corporations and regulatory agencies, including the SEC, on issues relating to federal and state securities disclosure obligations. ECF No. 427-3 ¶¶ 2-7. This knowledge and experience, which Plaintiffs do not dispute, is sufficient to conclude that the opinions in question are reliable.

That said, Coates may not testify before the jury about whether he believes that Twitter’s processes for preparing public disclosures are consistent or inconsistent with the customs and practices among large public companies. That factual determination is reserved for the jury. *See Oracle*, 2018 WL 6511146 at *7 (“An expert witness may not usurp the jury’s role in making fact determinations.”); *Daifotis*, 2012 WL 2051193 at *4 (excluding expert testimony evaluating how the defendant’s “process for communications with the public measured

up against industry standards” on the ground that “[t]hese are factual issues for the jury to consider after hearing the evidence at trial”).

In re Twitter, Inc. Sec. Litig., No. 16-CV-05314-JST, 2020 WL 9073168, at *10–11 (N.D. Cal. Apr. 20, 2020).

Here, Seiden’s testimony is reliable because of his extensive experience as a securities analyst, writing and reviewing analyst reports about biopharmaceutical companies in the clinical drug trial and FDA review process. *See* ECF No. 192-16 ¶¶ 1–6. Accordingly, Seiden may testify about industry practice regarding what types of information biopharmaceutical companies usually share to investors in the context of Phase 3 clinical trials and FDA regulatory review thereof because this is relevant and helpful to the jury’s assessment of Defendants’ scienter. But Seiden may not opine on whether Defendants’ disclosures were consistent with that practice because that would intrude upon the province of the jury to determine this issue of fact. *See In re Twitter*, 2020 WL 9073168, at *10–11.

Third, consistent with the reasons discussed previously, the Court excludes Seiden from testifying about analyst reports commenting on the post-Class Period approval of avacopan as TAVNEOS, including analyst reports on TAVNEOS’s label, because such opinions are irrelevant and risk confusion.

L. Defendants’ Motion to Exclude Testimony of Dr. Matthew Cain

Plaintiff intends to introduce the testimony of Matthew Cain, Ph.D., to opine on loss causation and damages. In his report, Cain constructed a “out-of-pocket damages model,” where the damages were “equal to the artificial inflation in the share price at the time of purchase minus the artificial inflation per share at the time of sale, or, if the share remains unsold prior [to] the full revelation of the alleged fraud, then damages are equal to the artificial inflation at the time of purchase, subject to the [PSLRA]’s 90-day lookback provision.” ECF No. 220-3 at 10 (quoting *Weston v. DocuSign, Inc.*, 2024 WL 2925979, at *8 (N.D. Cal. June 10, 2024)). In creating his damages model, Cain conducted an “event study,” which purported to “control[] for market and industry effects on ChemoCentryx’s stock price . . . to account for non-fraud related factors.” *Id.* After applying this methodology, Cain opined that ChemoCentryx’s stock price “declined by 42.94% and 62.21% on May 4 and 7, 2021, respectively, as the artificial inflation dissipated from

ChemoCentryx’s stock price.” *Id.* at 10–11. Dr. Cain’s event study also “demonstrated that the stock price declines on these two dates were statistically significant to the 99.9% confidence level.” *Id.* at 11. And after conducting a review of news and analyst reports for “confounding” information that may have contributed to the decline in stock price on those dates, Cain concluded that he found “no economic evidence of information unrelated to the Complaint’s claims that needs to be disaggregated from” the price decline on either date. *Id.* at 11 (quoting ECF No. 202-25 ¶¶ 136, 160–61).

Cain then “determined the amount of artificial inflation on each date of the Class Period,” through an “inflation ribbon” that used a “constant percentage” methodology—whereby the stock price was determined to have been inflated by a constant percentage through the Class Period—“because avacopan was constantly viewed throughout the Class Period by the market as ChemoCentryx’s primary driver of value.” *Id.* at 11–12.

1. Constant Percentage Methodology

Defendants argue that Cain’s constant percentage method is unreliable because (1) he “does not identify the effects on the stock of any of the 140 allegedly false and misleading statements, and instead just assumes that because the stock fell by 78%, it was inflated at all times during the Class Period by that same percentage;” (2) his “price maintenance” methodology does not match the facts of the case; and (3) his methodology produces “varying and inconsistent results across investors.” ECF No. 202-3 at 16. The Court does not find that these objections render Cain’s methodology so unreliable as to justify the exclusion of his testimony.

First, Defendants have cited no authority requiring plaintiffs in a securities case to calculate the precise amount that each allegedly misleading statement—and there are 140 such statements in this case—had on the stock price during the Class Period. Instead, courts regularly find that the constant percentage inflation methodology used by Cain is reliable and appropriate in circumstances such as those alleged here. *See In re Valeant Pharms. Int’l, Inc. Sec. Litig.*, No. 3:15-cv-07658-MAS-LHG, 2023 WL 9748644, at *29–30 (D.N.J. May 22, 2023), *report and recommendation adopted as modified*, No. cv-15-7658-MAS-RLS, 2024 WL 708831 (D.N.J. Jan. 2, 2024), *reconsideration denied*, No. cv-15-7658 (MAS), 2024 WL 1975499 (D.N.J. May 3,

2024) (collecting cases); *see also Police Ret. Sys. of St. Louis v. Granite Constr. Inc.*, 2021 WL 229310, at *7 (N.D. Cal. Jan. 21, 2021) (noting at the class certification stage that determining “how ‘inflation per share may have evolved over the Class Period[.]’ . . . can be accomplished via . . . ‘constant percentage inflation’”); *Baker v. SeaWorld Ent., Inc.*, 423 F. Supp. 3d 878, 908 (S.D. Cal. 2019) (noting that “constant percentage inflation [is a] commonly utilized theory in securities fraud cases”).

Second, Cain has sufficiently established a basis for his price maintenance methodology for proving loss causation. Cain opines that ChemoCentryx’s stock price soared when Defendants first misled investors at the beginning of the Class Period about the results of the ADVOCATE study. *See* ECF No. 220-3 at 15. He further opines that Defendants’ subsequent misleading statements and omissions over the remainder of the Class Period were substantially identical to their prior ones, thus maintaining the artificially inflated price of ChemoCentryx’s stock without further inflating it. *See id.* Plaintiff thus argues that a price maintenance model is appropriate for this case, as “avacopan’s expected value (relative to the Company’s overall value) did not materially change during the Class Period,” and avacopan was “ChemoCentryx’s lead drug candidate throughout the Class Period, with analysts consistently reporting that their recommendations to buy ChemoCentryx stock was based on avacopan.” ECF No. 220-3 at 16.

Cain’s application of a price maintenance methodology is thus distinguishable from the cases cited by Defendants, none of which involved an event study establishing a causal link between a corrective disclosure and a decline in stock price. In *In re Credit Suisse First Boston Corp.*, the court found that there was no evidence that the allegedly fraudulent reports had any effect on the market and was therefore “not persuaded that the absence of a report would have an effect on the market.” *In re Credit Suisse First Bos. Corp. (Lantronix, Inc.) Analyst Sec. Litig.*, 250 F.R.D. 137, 143 (S.D.N.Y. 2008). The court then concluded that because “there is no way to test [the expert’s] [price maintenance] theory, it is based not on facts but on speculation.” *Id.* at 145. Similarly, in *In re Northern Telecom Ltd. Security Litigation*, the challenged expert did not perform an event study at all and merely speculated that the defendants’ omissions artificially maintained the price of their stock without any evidence or statistical analysis. 116 F. Supp. 2d

1 446, 461 (S.D.N.Y. 2000).

2 While Defendants argue that Cain merely assumes what he sets out to prove—i.e., that
3 each of the alleged misleading statements caused the inflation or maintenance of ChemoCentryx’s
4 stock price—Defendants mischaracterize the nature of Cain’s report. “To prove loss causation,
5 plaintiffs need only show a ‘causal connection’ between the fraud and the loss,” one method of
6 which can be where a plaintiff shows that “the stock price fell upon the revelation of” a fraud. *See*
7 *Mineworkers’ Pension Scheme v. First Solar Inc.*, 881 F.3d 750, 753–54. (9th Cir. 2018). Cain’s
8 event study on the two corrective disclosures in May 2021 sufficiently asserts a reliable theory of
9 loss causation connecting the revelation of the alleged misrepresentations and the drop in
10 ChemoCentryx’s stock price. As discussed above, Cain conducted an event that controlled for
11 market and industry effects and found that those declines were statistically significant to the
12 99.9% confidence level. Cain has thus sufficiently grounded his opinions in statistical and
13 qualitative analysis. And while Defendants identify critiques of his methodology and
14 assumptions, including his price maintenance model, they can raise these critiques during cross-
15 examination. *See In re Twitter, Inc. Sec. Litig.*, No. 16-CV-05314-JST, 2020 WL 13863616, at *9
16 (N.D. Cal. Jan. 28, 2020) (“These [disputes over how variables were factored into the analysis] are
17 matters for cross-examination, not exclusion.”).

18 Third, Defendants’ argument that Cain’s constant percentage methodology produces
19 inconsistent results for investor recovery based on when they purchased the stock goes towards the
20 weight of his testimony—not its admissibility. As other courts have recognized in admitting
21 constant percentage methodologies, “[t]o the extent that Defendants suggest there is the possibility
22 that Plaintiffs would recover losses that are non-fraud related, Defendants have not shown the risk
23 undermines the reliability of the analysis as a whole. This argument tends to go towards the
24 probative value of the testimony to be addressed at trial for the jury to consider.” *In re Novatel*
25 *Wireless Sec. Litig.*, No. 08CV1689 AJB (RBB), 2013 WL 12144150, at *11 (S.D. Cal. Oct. 25,
26 2013); *see also In re Valeant Pharms. Int’l, Inc. Sec. Litig.*, 2023 WL 9748644, at *30.

27 **2. Disaggregation of Confounding Variables**

28 Defendants further argue that the Court should exclude Cain’s opinions on damages

1 because he fails to disaggregate from the declines in stock price all non-fraudulent causes of that
2 decline. ECF No. 202-3 at 20. Defendants cite the following examples of non-fraudulent causes
3 that contributed to ChemoCentryx’s decline in stock price on May 4, 2021, and May 7, 2021: (1) a
4 “confusing” regulatory history discussion by the FDA and the “unexpectedly negative tone of the
5 FDA’s commentary in the Briefing Book” and (2) the actual, mixed voting results of the experts
6 during the Advisory Committee (“AdCom”) meeting. *Id.* at 22–24.

7 Plaintiff counters that these criticisms go to the weight of Cain’s testimony—not its
8 admissibility. They further argue that while the developments identified by Defendants may have
9 surprised investors and affected the stock price, they were foreseeable to *Defendants* who had
10 withheld the information reflected in these developments. *See* ECF No. 220-3 at 20–21 (providing
11 table of statements matching up the negative statements in the Briefing Book with concerns that
12 the FDA had privately communicated to ChemoCentryx during the Class Period).

13 Defendants rely heavily on *In re FibroGen Securities Litigation* to argue that an
14 “‘AdCom’s decision not to recommend approval’ of a drug is itself a significant, nonfraudulent
15 development that impacts stock prices.” *See* ECF No. 248-6 at 14 (quoting *In re FibroGen Sec.*
16 *Litig.*, No. 21-CV-02623-EMC, 2024 WL 1064665, at *12 (N.D. Cal. Mar. 11, 2024)). In that
17 case, the court found that the Advisory Committee’s vote to recommend not to approve the drug
18 Roxadustat could not form the basis of a corrective disclosure because it was a “development that
19 FibroGen learned about at the AdCom itself, and therefore is not itself a correction of a previous
20 misstatement,” and none of the other information discussed at the meeting was new to investors.
21 *See In re FibroGen Sec. Litig.*, 2024 WL 1064665, at *12–15.

22 But under Plaintiff’s theory of fraud, “the adverse AdCom discussion and related vote
23 were foreseeable to ChemoCentryx . . . [because] Defendants were told repeatedly and for years
24 that the FDA had grave concerns about the results and the design of the ADVOCATE trial” but
25 misrepresented their communications with the FDA and their prospects for approval as positive
26 and straightforward to their investors. *See* ECF No. 220-3 at 25. Indeed, Cain testifies that even
27 after the May 4, 2021 Briefing Book was released, ChemoCentryx continued to mislead investors
28 by downplaying the FDA’s concerns and suggested that the upcoming AdCom meeting would

yield clarity and a positive vote. *See* ECF No. 202-25 ¶¶ 117–133. So unlike in *FibroGen*, Plaintiff contends that the outcome of the AdCom vote was related to Defendants’ prior misstatements and was corrective of those misstatements when revealed. Cain can thus reasonably conclude that the result of the AdCom vote is not a nonfraudulent cause of the stock price drop that needs to be disaggregated. *See In re AVEO Pharms., Inc. Sec. Litig.*, No. CV 13-11157, 2017 WL 5484672, at *7 (D. Mass. Nov. 14, 2017) (finding that an FDA advisory committee meeting could form the basis of a corrective disclosure in part because “by offering their own view of the outcome of the [AdCom] meeting as it pertained to the likelihood of approval, Defendants created a link between approval . . . , over which any news was material to the market, and the actual outcome of the meeting”).

The other cases cited by Defendants are also distinguishable because they involved instances where factors that indisputably did not relate to fraud (and were even positive developments for stock price) pervaded the event study and the expert made no attempt to account for those factors such that the expert’s methodology was “flawed to the point of being unreliable.” *See In re REMEC Inc. Sec. Litig.*, 702 F. Supp. 2d 1202, 1273–74 (S.D. Cal. 2010); *see also Bricklayers & Trowel Trades Int’l Pension Fund v. Credit Suisse First Bos.*, 853 F. Supp. 2d 181, 190–91 (D. Mass. 2012), *aff’d sub nom. Bricklayers & Trowel Trades Int’l Pension Fund v. Credit Suisse Sec. (USA) LLC*, 752 F.3d 82 (1st Cir. 2014) (finding that “confounding factors pervade Dr. Hakala’s event study” because of “the extraordinary volume of AOL-related news in the marketplace during the Class Period” about different aspects of AOL’s business and that were a mix of positive and negative).

Here, Cain has made an effort to account for nonfraudulent news and developments that may have contributed to ChemoCentryx’s decline in stock price. He included an extensive review of the analyst and news commentary on the corrective disclosure dates and includes in his report analysis of that commentary before concluding that “there was no confounding information that requires disaggregation from the CCXI common stock price decline on May 7, 2021.” *See* ECF No. 202-25 ¶¶ 99–161. That Defendants disagree with his conclusion does not mean that the methodology he employed in reaching that conclusion is unreliable.

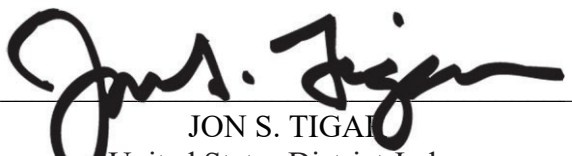
Defendants’ assertion that Cain failed to disaggregate confounding variables thus does not provide a basis for exclusion. While Defendants “certainly may argue to the jury that [Cain] did not reliably filter out other confounding variables that would have affected the stock price,” they have “not shown that [Cain’s] opinion is so unreliable that it must be excluded.” *S.E.C. v. Leslie*, No. C 07-3444, 2010 WL 2991038, at *15 (N.D. Cal. July 29, 2010); *see In re Groupon, Inc. Sec. Litig.*, No. 12 C 2450, 2015 WL 1043321, at *6 (denying motion to exclude for a purported failure “to take into consideration confounding information”). As Defendants themselves recognize in their briefing regarding Gibbons, “‘deficiencies in a statistical analysis,’ such as failure to consider relevant factors, generally ‘raise issues of weight rather than admissibility.’” *See* ECF No. 227-5 at 16 (quoting *Apple iPod iTunes Antitrust Litig.*, 2014 WL 4809288, at *6 (N.D. Cal. Sept. 26, 2014); *see also In re Twitter, Inc. Sec. Litig.*, 2020 WL 13863616, at *9 (“These [disputes over how variables were factored into the analysis] are matters for cross-examination, not exclusion.”)).

CONCLUSION

In sum, the Court grants Plaintiffs’ motions to exclude the testimony of Anupam Jena and Lindsay Lally. The Court denies Defendants’ motion to exclude the testimony of Matthew Cain. And the Court grants in part and denies in part, consistent with the discussion in this order, Defendants’ motions to exclude the testimony of David Madigan, Simon Helfgott, and Alan Bonder, and Plaintiff’s motions to exclude the testimony of Anisha Dua, Naga Chalasani, Steven Weisman, Robert Gibbons, and Carl Seiden.

IT IS SO ORDERED.

Dated: May 30, 2025


JON S. TIGAI
United States District Judge